

CLAIMS

1. A biospecific assay method in which
- microparticles coated with the bioaffinity reactant A binding the analyte to be assayed; the sample to be analyzed, and the labelled bioaffinity reactant B are
5 mixed, thus initiating the binding reaction between the bioaffinity reactant A, bioaffinity reactant B and the analyte,
- the signal strength from the labelled bioaffinity reactant B bound to the microparticles is quantitated for
10 the determination of the analyte concentration in the sample, characterized
- by the use in the assay of such an amount of sample and microparticles that after binding of the analyte of the sample to the said amount of microparticles, each
15 individual microparticle will emit such a signal strength as to allow the measurement of the analyte concentration of the sample over the whole range of typical analyte concentrations, and
- by separate measurement of the signal strength from each
20 microparticle.

2. The assay method according to claim 1, characterized by the adjustment of the amount of microparticles so as to allow the measurement of the lowest analyte concentration in the sample from individual microparticles by the
25 sensitive label technology used.

3. The assay method according to claim 1, characterized by the adjustment of the amount of microparticles so as to allow the measurement of the highest analyte concentration in the sample from individual microparticles by the
30 sensitive label technology used.

4. The assay method according to claim 2, characterized by the use of an increasing sample volume in the non-competitive assay and in the competitive assay.

5. The assay method according to claim 3, characterized by the use of a decreasing sample volume in the non-competitive assay and in the competitive assay.

5 6. The assay method according to claim 1, characterized by the assay being a non-competitive immunoassay, in which the labelled bioaffinity reactant B is an antibody directed against the antigen of the analyte.

Sub B2 7. The assay method according to claim 1, characterized by the assay being a nucleic acid hybridization assay, in
10 which the labelled bioaffinity reactant B is a nucleic acid probe.

15 8. The assay method according to claim 1, characterized by the assay being a competitive immunoassay, in which the labelled bioaffinity reactant B is an antigen, and the bioaffinity reactant A an antibody, for whose binding sites the labelled antigen and the antigen of the analyte compete.

20 9. The assay method according to claim 8, characterized by the control of the amount of microparticles coated with the antibody A so that the lowest analyte concentration will result in the strongest signal, when measuring individual microparticles by the label technology used.

Sub B37 25 10. The assay method according to claim 1, characterized by the use of labels emitting fluorescence, time-resolved fluorescence, chemiluminescence or bioluminescence.

11. The assay method according to claim 1, characterized by the microparticles used being a mixture of microparticles recognizing different analytes, thus allowing the simultaneous assay of several analytes in the same sample.

30 12. The assay method according to claim 11, characterized

by the identification of the microparticles recognizing different analytes by using fluorescence, time-resolved fluorescence, chemiluminescence or bioluminescence or their combinations.

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